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Comparative effectiveness, safety, and costs of surgical versus conservative treatment in patients with full-thickness rotator cuff tears

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Executive Summary

The Swiss Medical Board (SMB) assessed the evidence of clinical effectiveness and safety of surgical and conservative treatment of full-thickness rotator cuff tears and evaluated the economic implications, using standard methods for systematic reviews and health economic analysis. Based on this assessment, the present Appraisal Report was drafted using the Evidence-to-Decision (EtD) framework.

The assessment included three randomized, controlled trials (RCTs) in a total of 332 patients, and seven controlled nonrandomized studies (NRSs) in 656 patients. Duration of follow-up in these studies was up to 5 years. For one RCT, outcome data after 10 years of follow-up were reported only recently, and these were taken into account in this report. Outcome data of the RCTs in shoulder function and shoulder pain showed statistically significant differences in favor of surgery when compared to conservative treatment. However, the clinical relevance of these differences was questionable. Effect estimates for shoulder range of motion and muscle strength were similar after surgery and conservative treatment in the RCTs. In one study, the observed differences were still seen in the follow-up examination after 10 years. In the NRSs included in this assessment, shoulder function also showed statistically significant differences in favor of surgery, but clinical relevance of the difference was again uncertain.

The Appraisal Committee concluded that the differences in desirable effects were moderate. There was considerable imprecision in the estimates of undesirable effects due to the small number of adverse events reported. The absolute risk of re-tears after initial surgery appeared to be substantial. Overall, the differences between surgical and conservative treatments were small. The quality of the evidence was considered moderate to low for RCTs and very low for NRSs. The overall quality of the evidence was judged to be low. The Appraisal Committee concluded that the balance of desirable and undesirable effects was probably in favor of surgical treatment, although the advantages were of little clinical relevance. However, selected patient groups might benefit more from surgery.

The health economic analysis included a *de novo* cost analysis and a budget impact analysis. Both analyses were limited by shortcomings of the available data. Overall quality of the economic evidence was considered to be moderate. In a model using a 5-year time horizon, the estimated costs of surgical treatment exceeded those of conservative treatment by approx. CHF 7,000 per patient. The estimated budget impact of surgery amounted to approx. CHF 90 million per year in this model. The Appraisal Committee concluded that these resource requirements were large and that the economic evidence probably favored conservative treatment.

Furthermore, patients with rotator cuff tears are a heterogeneous group, and patient values may be variable. Both surgical and conservative treatments were judged to be acceptable and feasible in Switzerland, and there was no major concern with respect to health equity. Based on the limited evidence available, the Appraisal Committee issued a conditional recommendation in favor of surgical treatment of rotator cuff tears.

Abbreviations

ASES	American Shoulder and Elbow Surgeons
CHOP	Schweizerische Operationsklassifikation (Swiss classification of surgical interventions)
CI	Confidence interval
CMS	Constant-Murley score
DRG	Diagnosis-related group
EtD	Evidence to Decision
HTA	Health technology assessment
ICD-10	International Classification of Diseases 10
ICER	Incremental cost-effectiveness ratio
MCDI	Minimal clinically important difference
MRI	Magnetic resonance imaging
NRS	Nonrandomized study
PICO	Population, intervention, control, outcome
QALY	Quality-adjusted life year
RCT	Randomized controlled trial
RR	Relative risk
SF-36	Short-form 36
SMB	Swiss Medical Board
VAS	Visual analogue scale

1. Background

Tears of the rotator cuff of the shoulder joint represent a common musculoskeletal injury and are diagnosed in people with and without shoulder symptoms. Such injuries are either traumatic or nontraumatic, with the latter mostly of degenerative origin. In the general population, overall prevalence of rotator cuff tears has been reported to be more than 20% and is known to increase with patient age. The present health technology assessment (HTA) is restricted to full-thickness tears of the rotator cuff tendons. These lesions can be classified according to their size (small, medium, large), number of affected tendons, degree of tendon retraction from the bony insertion, or extent of sequelae (e.g. fatty degeneration or atrophy of the affected muscles).[1] In a systematic review, the prevalence of full-thickness rotator cuff tears in symptomatic patients was 35% when assessed with ultrasonography, and 41% when assessed with magnetic resonance imaging (MRI).[2] In asymptomatic patients, the prevalence was 22% (ultrasonography) and 10% (MRI). Mean age of these populations ranged from 44 to 50 years.[2]

Rotator cuff tears may impair shoulder function, activities of daily living, and quality of life. Such injuries result in substantial utilization of healthcare resources, absenteeism from work, and disability. Therapeutic options include surgical and conservative (i.e. nonsurgical) treatment. The primary aim of either approach is to alleviate symptoms and restore shoulder function. Surgery involves arthroscopic, open, or mini-open techniques and employs a variety of methods, such as suture, reconstruction, re-insertion, or re-fixation. Conservative treatment commonly consists of physiotherapy (e.g. exercises or manual therapy), advice on 'activity' (e.g. temporary activity modifications), oral pain medication, or steroid injections. Both surgical and conservative treatments have been shown to improve clinical outcomes, but a comprehensive HTA and evidence-based recommendations for care in Switzerland are still lacking.

2. Methods

In the formal scoping process, the PICO (population, intervention comparison, outcome) questions were defined in consultation with stakeholders. Evidence of clinical effectiveness and safety as well as health economic evidence were then assessed using the methods described in detail in the corresponding Assessment Report. First, a systematic review identified and assessed the research evidence from randomized controlled trials (RCTs) and nonrandomized controlled studies (NRSs) published up to May 2018. These studies included patients with traumatic or degenerative full-thickness rotator cuff tears who underwent surgical or control interventions. Eligible control interventions included any conservative treatment, no treatment, or 'watchful waiting'. Second, the health economic assessment consisted of a systematic review of the health economic literature, a *de novo* cost analysis with supplemental cost-effectiveness considerations, and a budget impact analysis based on a health insurance perspective.

The Appraisal Committee discussed the results of the assessment in two meetings held in May 2019 and September 2019, using the Evidence-to-Decision (EtD) framework.[3] Recommendations were formulated based on the available evidence and additional considerations including feedback from stakeholders during the first meeting. The EtD framework considers several domains such as the balance between desirable and undesirable effects, quality of evidence, cost-utility/resource requirements, patient values, health equity, and acceptability/feasibility of the intervention. Differences in desirable and undesirable effects were categorized as large, moderate, small, or trivial.

The resulting recommendations were formulated as 'strong' or 'conditional' in favor of a given intervention, in favor of either the intervention or comparator, or against the intervention. Recommendations were supplemented by considerations regarding subgroups, implementation aspects, monitoring and evaluation, and research priorities.

3. Results of the appraisal

3.1 Evidence of clinical effectiveness and harm

3.1.1 Desirable effects

Evidence of desirable effects in RCTs and NRSs was analyzed separately due to the differences in study designs and the potential bias resulting from this.

3.1.1.1 Evidence from randomized studies

The three RCTs included in this analysis were conducted in Finland (173 participants)[4], the Netherlands (56 participants)[5], and Norway (103 participants)[6] and were published between 2010 and 2015. In total, 332 patients with 339 affected shoulders were investigated. Overall, 197 shoulders were assigned to surgical treatment and 142 to conservative treatment.

Shoulder function was measured with the Constant-Murley score (CMS; 0 [worst] to 100 [best]) and shoulder pain with the visual analogue scale (VAS; 0 [best] to 10 [worst]) at 12, 24, and 60 months. Effect estimates showed statistically significant differences in favor of surgery when compared to conservative treatment. For example, at 12 months, the mean CMS for shoulder function after surgery exceeded that after conservative treatment by 6.9 points (95% confidence interval [CI]: 1.6 to 12.3 points). For shoulder pain (VAS), the mean difference was 1.1 in favor of surgery (95%CI: 0.4 to 1.8). In the literature, the minimal clinically important differences (MCID) were 10.4 points for the CMS (shoulder function) and 1.4 for VAS (pain).[7,8] Consequently, the clinical relevance of the above-mentioned differences is questionable.

Effect estimates for shoulder range of motion and muscle strength (both measured with subscores of CMS) after surgery and conservative treatment did not differ at 12, 24, or 60 months.

3.1.1.2 Evidence from nonrandomized studies

The seven NRSs included in this analysis were published between 2000 and 2018; all but one study (with two publications) were based on retrospective data. The NRSs were conducted in Europe (two studies; 81 participants)[9,10], Asia (three studies; 406 participants)[11–13], and North America (two studies; 169 participants).[14,15] Overall, 343 patients were assigned to surgery and 313 to conservative treatment. In total, 656 patients (with 656 affected shoulders) participated in these NRSs, with 93 of them participating in a prospective study. Study duration, i.e. the time from treatment allocation (baseline) to last follow-up, ranged from 2 months to 60 months.

Both after 18 months and 50 to 60 months, shoulder function (CMS) was significantly better after surgery than after conservative treatment. The differences in CMS scores between surgically and conservatively treated patients were 11.6 points (95%CI: 8.8 to 14.3 points) after 18 months and

7.6 points (95%CI: 1.2 to 14.0 points) after 50 to 60 months. Considering the reported MCID for shoulder function (see above), the clinical relevance of these differences was, however, questionable.

3.1.1.3 Additional considerations

The results of the 10-year follow-up of the Norwegian RCT were published in June 2019 (i.e. after the cut-off date for this assessment).[16] Of the 103 participants, 90 were assessed after 10 years, and the results were as follows:

Shoulder function was better after surgery; CMS scores were 9.6 points (95%CI: 3.6 to 15.7 points) higher when compared to the group of patients treated conservatively. The American Shoulder and Elbow Surgeons (ASES) score was 15.7 points (95%CI: 9.3 to 22.1 points) higher after surgery. For shoulder pain, the mean difference in VAS was 1.8 (95%CI: 1.1 to 2.6) in favor of surgery. The differences in pain-free range of motion were 19.6 degrees (95%CI: 5.6 to 33.6 degrees) for abduction and 14.3 degrees (95%CI: 3.3 to 25.3 degrees) for flexion, both in favor of surgery. The mean difference in muscle strength was 1.8 kg (95%CI: -0.2 to 3.8 kg), but this was not statistically significant. The overall quality of life (SF-36) showed only small, nonsignificant differences between the groups. The authors concluded that the difference between surgical and conservative treatments after 10 years was statistically significant for most reported outcomes, but their clinical importance was questionable.

3.1.1.4 Judgment

The Appraisal Committee concluded that the differences in desirable effects between surgical and conservative treatments were moderate.

3.1.2 Undesirable effects

3.1.2.1 Evidence from randomized studies

In the three studies included in this analysis, the risk of *any* adverse event did not differ significantly between surgical and conservative treatments (RR 1.5; 95%CI: 0.5 to 4.3). None of the reported adverse events were related to treatment. Because re-tear rates were only relevant to patients treated surgically, the outcome “failed surgery” was not compared between groups. One study reported a re-tear rate of 74% (14 of 19 patients) at 12 months.[5] Another study reported rates of full-thickness re-tears of 8% (4 of 50 patients) at 12 months and 13% (8 of 60 patients) at 60 months.[6]

3.1.2.2 Evidence from nonrandomized studies

Treatment failure was defined as re-tear of tendons in the group of patients treated surgically and progression of the tear in the group treated conservatively. In one study, the reported re-tear rate was 10% (2 of 20 patients) at 18 months.[9] The proportions of conservatively treated participants with tear progression ranged between 11% and 67%.

3.1.2.3 Additional considerations

Of the 47 participants in the Norwegian RCT who had undergone a 10-year follow-up examination after surgery, 16 (34%) had experienced full-thickness re-tear. Their shoulder function (CMS) was significantly impaired when compared to those with intact tendon repair.[16] In turn, of the 51

participants treated conservatively, 14 (27%) had an unsatisfactory treatment result and had switched to secondary surgery (12 patients within the first 2 years and 2 patients after 5 to 10 years).

3.1.2.4 Judgment

The Appraisal Committee concluded that the number of adverse events in the analyses was small (resulting in imprecision of estimates) and that differences in undesirable effects between surgical and conservative treatments were small.

3.1.3 Overall quality of evidence

The quality of evidence was rated as moderate for the outcome 'shoulder function' and low for the outcome 'pain'. Furthermore, quality of evidence was rated as moderate for shoulder range of motion and muscle strength and low for adverse events. Although the effect estimates were of similar size, the quality of evidence differed between randomized and nonrandomized studies as detailed below:

In the RCTs, quality of evidence was considered moderate to low. This can be explained by (i) a possible risk of performance bias and detection bias due to the nature of the studies, as adequate blinding was not possible (for details see Assessment Report); (ii) lack of clinical relevance of the observed effects, particularly regarding the lower limit of the 95% CI in the assessment of shoulder function and pain; or (iii) the 95% CIs that were consistent with the possibility of both benefit and harm (dichotomous outcome: adverse events) or the possibility of both improving and worsening of symptoms (continuous outcomes: shoulder range of motion and muscle strength).

In the NRSs, the quality of evidence was very low. This can be explained by (i) a very high risk of bias due to major confounding, selection bias, and lack of blinding applying to all outcomes; (ii) lack of clinical relevance; (iii) 95% CIs that were consistent with the possibility of both improving and worsening of symptoms (pain and range of motion); or (iv) inadequate group sizes (i.e., low number of patients or varying group sizes) in one study.

3.1.3.1 Additional considerations

Data from the 10-year follow-up of the Norwegian RCT were not included in the formal assessment of the quality of evidence.[16]

3.1.3.2 Judgment

The overall quality of evidence was judged to be low.

3.1.4 Balance between desirable and undesirable effects

The findings for some patient-relevant outcomes (i.e. shoulder function and pain) suggest that surgery may be marginally more effective than conservative treatment. However, clinical relevance of the differences remains questionable. For other patient-relevant outcomes (i.e. shoulder range of motion, muscle strength, quality of life, and adverse events), the limited data available did not show any differences between the study groups. Adverse events were poorly reported. In most of the studies, they were either not addressed (particularly in the NRSs) or insufficiently defined, or it was unclear whether the data on undesirable effects had been collected systematically.

3.1.4.1 Additional considerations

A strength of the systematic review conducted for this assessment is its consideration of the best available evidence from both the RCTs and NRSs. Based on the registered and unpublished studies that were identified, additional results from randomized studies that are currently ongoing can be expected only in the year 2022.

The average age of the patient populations in the studies included was relatively high (58 to 70 years), but this did not reflect the clinical experience made by Swiss orthopedic surgeons who were consulted for this appraisal. On this occasion, orthopedic surgeons put forward that considerable advances in surgical technique have been made in the past 30 years, while conservative treatment has not advanced to the same extent. Moreover, patient numbers and surgeon experience in the trials included in the assessment may have influenced the outcomes.

3.1.4.2 Judgment

The Appraisal Committee concluded that the balance of desirable and undesirable effects is probably in favor of surgical treatment.

3.2 Considerations about resource requirements

3.2.1 Evidence

3.2.1.1 De novo cost analysis

The calculated cost models considered various time frames: Within 6 months after initial repair surgery plus subsequent physiotherapy, costs per patient amounted to CHF 10,458, while for conservative treatment (physiotherapy) alone, costs amounted to CHF 1,018. Thus, initial surgery was approx. 10 times more costly than conservative treatment (cost difference of CHF 9,440). The surgical intervention itself constituted the highest cost factor (CHF 9,379), followed by the subsequent physiotherapy (CHF 773 for 18 sessions).

For the 5-year period after the intervention, estimated costs of initial repair surgery plus physiotherapy amounted to CHF 10,662 per patient, while the costs for conservative treatment alone amounted to CHF 3,599 per patient. Thus, the difference between the two treatment strategies was CHF 7,063. The deterministic sensitivity analysis of this model showed that these results were strongly influenced by surgery costs, followed by the overall rate of patients switching from conservative treatment to surgery within 24 months. All other variables had only minor impact.

It was not possible to perform a proper *de novo* cost-effectiveness analysis. Neither international data for cost-effectiveness that could have been adapted to Switzerland nor estimates of quality of life of patients undergoing surgery or conservative treatment were available. In supplemental calculations, it was determined what differences in quality-adjusted life years (QALYs) between the two treatment strategies are necessary (for periods of 2 or 5 years) in order to achieve incremental cost-effectiveness ratios (ICERs) of either CHF 50,000 or CHF 100,000 per QALY gained:

An ICER of CHF 100,000 was regarded as more relevant to Switzerland; the estimated cost difference for the 2-year period was CHF 6,992 and resulted in a QALY difference of 0.070. For the 5-year period, the estimated cost difference was CHF 7,063 which resulted in a similar QALY difference (0.071).

3.2.1.2 Budget impact analysis

Considering only the initial 6-month period of treatment of full-thickness rotator cuff tears, the average annual costs of initial surgery amounted to CHF 131.9 million for the years 2018 to 2022, compared to CHF 12.8 million for the conservative treatment strategy (i.e. approximatively one tenth of costs associated with surgical repair). Consequently, the calculated difference (budget impact) between the two treatment approaches amounted to CHF 120 million per year.

For the 5-year time frame, the average annual costs of the initial surgery strategy amounted to CHF 134.5 million. The costs associated with the conservative treatment strategy amounted to CHF 45.4 million (i.e. approximatively one third of the costs incurred by surgery). The difference (budget impact) amounted to about CHF 90 million per year.

3.2.2 Additional considerations

The 10-year follow-up data for patients in the Norwegian RCT provided some limited evidence that the switch to surgery may occur later than after 24 months.[16] This may impact on the results of the *de novo* cost analysis.

3.2.3 Quality of evidence with regard to resource requirements

The health economic analysis was strengthened by the use of high-quality national routine data and the testing of two different approaches to identify eligible cases for surgery. First, combining relevant diagnosis-related group (DRG) codes with ICD-10 codes and Schweizerische Operationsklassifikation (Swiss classification of surgical interventions, CHOP) codes turned out to be potentially misleading due to the limited suitability of DRG codes for patient identification. The second approach focused on the combination of ICD-10 codes and CHOP codes and permitted a broader but probably more accurate selection of patients resulting in a more realistic cost estimation.

Some of the limitations listed below are applicable to both the assessment of evidence of clinical effectiveness/safety and health economics:

1. Long-term follow-up data of included studies were largely missing, and during the reported follow-up periods, additional treatments were not always described clearly. Only the Norwegian RCT had a follow-up period of more than 2 years, but the sample size (n=103) was rather small. Any end-stage costs (e.g. need for prosthesis) were not included in the models.

2. Inclusion criteria of the studies were broad and did not specify if eligible patients were pretreated or not. None of the RCTs enrolled participants at the time of injury but included patients who had already received initial (conservative) treatment. Mean duration between onset of symptoms and study enrolment ranged from 1 to 2.5 years. Furthermore, study populations were mixed because patients starting with conservative treatment could switch to surgery.

3. Patients with traumatic multiple-tendon tears were greatly underrepresented in the RCTs. They may require different assumptions, and any estimates from the current models may not apply to them.

4. The *de novo* cost analysis assumed that surgery for rotator cuff tears is performed during a hospital stay (reflecting current practice in Switzerland). However, in the USA and Nordic countries, the surgery is also performed in the outpatient setting. Related patient preferences are unknown.

5. There are alternatives to repair surgery, such as total reverse shoulder arthroplasty. However, these surgical interventions were not within the scope of the assessment.

6. Re-tears after repair surgery are frequent (see above) but were not accounted for in the present cost model. According to clinical experts, most patients with re-tears are asymptomatic and require neither additional surgery nor other treatment. The detection of re-tears in the clinical trials was driven by pre-planned follow-up examinations rather than participants' symptoms.

7. In the budget impact analysis, it was not possible to determine the annual number of patients who underwent conservative treatment in Switzerland. The estimated costs were based on DRG costs from 2014 projected to the year 2018.

8. The total costs from a societal perspective tend to be much higher than the direct medical costs alone. Indirect costs include sickness leave (e.g. when undergoing surgery or physiotherapy) and loss of productivity. It is difficult to estimate their relative importance.

3.2.4 Judgment

With a difference of about CHF 7,000 between treatment options, the resource requirements were judged to be large. Given the limitations mentioned above, the overall quality of economic evidence was considered moderate. The Appraisal Committee concluded that this evidence probably favors the conservative treatment strategy.

3.3 Patient values

A search of published evidence of patient values in relation to treatment of rotator cuff tears was not part of the assessment. It can be assumed that subgroups of patients vary with regard to the importance they attribute to treatment outcomes after rotator cuff tears, such as shoulder function or pain. For instance, younger patients with traumatic lesions (e.g. from playing sports) may value fast regaining of shoulder function to a larger extent than older patients with lesions of degenerative origin.

3.3.1 Judgment

The Appraisal Committee considered that important variability in patient values is likely.

3.4 Health equity

A search of published evidence of health equity in relation to treatment of rotator cuff tears was not part of the assessment. The Appraisal Committee discussed to what extent specialized surgical care for rotator cuff tears is available in the private sector (rather than the public sector), and whether this may disadvantage patients with mandatory health coverage only.

3.4.1 Judgment

The Appraisal Committee concluded that there is probably no impact on health equity.

3.5 Acceptability

A search of published evidence of the acceptability of treatment of rotator cuff tears was not part of the assessment.

3.5.1 Judgment

The Appraisal Committee concluded that surgery for rotator cuff tears can be regarded as an established procedure that is accepted by key stakeholders including patients and healthcare providers. This judgment excludes any consideration of effectiveness or safety of the intervention.

3.6 Feasibility

Surgery for rotator cuff tears is available in routine healthcare in Switzerland. Of note, several centers of excellence are available in the private sector.

3.6.1 Judgment

The Appraisal Committee concluded that surgery for rotator cuff tears is a feasible intervention from a technical and organizational point of view.

4. Recommendations

The Appraisal Committee issues a conditional recommendation in favor of surgical treatment of full-thickness rotator cuff tears.

Justification

The available evidence of clinical effectiveness and safety is limited but suggests that the balance of effects might be in favor of surgery. This seems to be confirmed by the 10-year follow-up data of a single randomized trial. However, the benefits of surgery are of questionable clinical relevance and are counter-balanced by relatively large costs and a substantial risk of re-tear of rotator cuffs.

Subgroup considerations

The consulted clinical experts indicated that some groups of patients with rotator cuff tears are likely to benefit from surgery more than do others. Relevant factors could be the etiology of the tear (traumatic vs. nontraumatic), anatomic nature (single vs. multiple tendon tear), or patient characteristics. However, the available studies failed to corroborate these claims.

Implementation considerations

Effective communication with patients is of prime importance to enable shared decision making. Patients' perception of treatment options and their preferences and values should be well understood before a decision is made.

Monitoring and evaluation

A prospective disease registry with standardized data collection would help to monitor and evaluate current routine care for rotator cuff tears in Switzerland. In addition, some aspects of care could be included in the existing monitoring systems. For instance, surgical site infections are monitored continuously within the Swissnoso network, but shoulder surgery has not been included so far.

Research priorities

Long-term studies investigating the effectiveness and safety of surgery or conservative treatment of rotator cuff tears are needed, especially since differences in outcomes appear to persist up to 10 years after initial treatment. Future research should focus on developing clinical guidelines to identify patients with full-thickness rotator cuff tears who are likely to benefit from surgery and those who face an increased risk of re-tears after surgery. The health condition is frequent, but the few available studies are of small size. Consequently, the Appraisal Committee recommends a joint research effort by specialized centers (e.g. in a sufficiently large multicenter RCT) to answer remaining questions about the best care for patients with rotator cuff tears. Furthermore, well-designed cost-effectiveness studies should provide a more reliable database for future health economic assessments.

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